K052783

OCT 27 2005

510(k) Summary
per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation (BSC) Two Scimed Place Maple Grove, MN 55311
Contact Name and Information	Diane Brinza Specialist, Regulatory Affairs Phone: 763-694-3061 Fax: 763-694-6966 e-mail: brinzad@bsci.com
Date Prepared	September 30, 2005
Proprietary Name(s)	IQ™ Guide Wire
Common Name	Catheter Guide Wire
Product Code	DQX
Classification of Device	Class II, 21 CFR Part 870.1330
Predicate Device	IQ™ Guide Wire K040140 February 12, 2004
Device Description	The IQ™ Guide Wires are silicone-coated, steerable, spring-coil guide wires available in a nominal diameter of 0.014 inches (0.36 mm) and nominal lengths of 185 and 300 centimeters with Brachial and Femoral marks at 90cm and 100cm respectively. The tip has Floppy flexibility, while the rail offers Moderate Support (MS). The distal two centimeters of all models are radiopaque and available in either a straight shapeable or a pre-formed J-Tip. The IQ™ Guide Wires will be available with and without a lesion length marker system. The 185-centimeter version is designed with a proximal extension section that allows connection to the AddWire™ Extension Wire.

Intended Use of Device	The IQ™ Guide Wires are intended to facilitate the placement and exchange of balloon dilatation catheters or other therapeutic devices during PTCA or PTA or other intravascular interventional procedures. The IQ™ Guide Wires are not intended for use in the cerebral vasculature. The devices are provided non-pyrogenic, sterile, and intended for one procedure only.
Technological Characteristics	The IQ™ Guide Wires utilize similar materials and methods of construction as the IQ™ Guide Wires (K040140, February 12, 2004). The IQ™ Marker version also has marker coils.
Non-Clinical Test Summary	Bench, product shelf life, and biocompatibility test results verified that the IQ™ Guide Wires met all of the specified requirements and are suitable for their intended use. The IQ™ Guide Wires are considered substantially equivalent to guide wires currently marketed by Boston Scientific based on a comparison of intended use, design and the results of *in vitro* testing and evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2005

Boston Scientific Corporation
c/o Ms. Diane Brinza
Specialist, Regulatory Affairs
Two Scimed Place
Maple Grove, MN 55311

Re: K052783
IQ™ Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: II
Product Code: DQX
Dated: September 30, 2005
Received: October 3, 2005

Dear Ms. Brinza:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K052783

Device Name IQ™ Guide Wire

Indications For Use

The IQ™ Guide Wires are intended to facilitate the placement of balloon dilatation catheters or other therapeutic devices during PTCA, PTA, or other intravascular interventional procedures.

The IQ™ Guide Wires are not intended for use in the cerebral vasculature.

Prescription Use X AND/OR Over-The-Counter Use_____
(Per Part 21 CFR §801 Subpart D) *(21 CFR 801 Subpart C)*

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052783